Updated Guidance for the Use of CSL™ 2009 H1N1 Monovalent Vaccine

November 19, 2009

Background

On November 11, 2009, the FDA expanded the approved use of CSL's™ seasonal and 2009 H1N1 monovalent influenza vaccines to include children aged 6 months and older. Both vaccines had previously been approved only for use in adults, aged 18 years and older. The immediate effect on the national 2009 H1N1 monovalent flu vaccination program is that CSL's™ 0.5 mL pre-filled syringe and 5 mL multi-dose vial formulations can now be used in a substantially broader range of ages. Currently, CSL™ 0.25 mL pre-filled syringes of 2009 H1N1 monovalent influenza vaccine are not available for use in the United States. CDC is making a programmatic recommendation and issuing clarifying guidance on use of CSL™ 2009 H1N1 monovalent vaccine that takes into account practical logistical considerations of allocation, ordering, and distribution of vaccine and ancillary supply kits.

Recommendation

Both the CSL™ 2009 H1N1 0.5 mL pre-filled syringe and multi-dose vial vaccine formulations should be reserved for use in individuals aged 3 years and older if alternative products are available to administer to children aged 6-35 months.

Rationale

Pre-filled syringe presentation: In order to prevent wasting vaccine, the CSL™ 2009 H1N1 0.5 mL pre-filled syringe is not recommended for use in children aged 6-35 months. Children aged 6-35 months require two 0.25 mL doses of vaccine separated by a minimum of 28 days. Using the CSL™ 2009 H1N1 0.5 mL pre-filled syringe to vaccinate children aged 6-35 months would result in wastage of one 0.25 mL dose per syringe. Unused 0.25 mL doses should not be reserved to administer to the same patient at a later time, or to another individual. Furthermore, transfer of vaccine content from one syringe to another is not permissible. Therefore, remaining partial doses must be discarded. With the current limited availability of vaccine nationwide, CDC discourages using a half dose of CSL™ H1N1 0.5 mL pre-filled syringe vaccine in children aged 6-35 months.

Multi-dose vial presentation: Due to logistical restrictions related to ancillary supply kits, CDC recommends that the CSL™ 5 mL multi-dose vaccine formulation be used in individuals aged 3 years and older.

The quantities of ancillary supplies (needles, syringes, vaccination records, and alcohol prep pads) available with each order of multi-dose vial vaccine were intended for administration of a 0.5 mL dose per patient. Providers can choose to administer half doses (0.25 mL) from the multi-dose vial formulation to children aged 6-35 months, if they are able to supply their own needles, syringes, alcohol prep pads, and to print out additional vaccination records from the CDC website (http://www.cdc.gov/flu/freeresources/2009-10/pdf/influenza_record_card2009.pdf).

Questions?

If you have any questions or need clarification on this guidance please contact the CDC Immunization Desk at EOCImmunization@cdc.gov.